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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,916	10/02/2000	Carl Anthony Blau	UOFW115624	4343

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,916

Applicant(s)

BLAU ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 43,54,67-69 and 77-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42,44-53,55-66 and 70-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and arguments received on 3/6/06 have been entered. Claims 1-88 are pending in the instant application. This application contains claims 43, 54, 67-69, and 77-88 drawn to an invention nonelected without traverse in Paper No. 12. Claims 1-42, 44-53, 55-66, and 70-76 are currently under examination. The applicant is further reminded that the species election of "hematopoietic stem cells" still stands, although the claims have not been so limited. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in a previous office action.

Oath/Declaration

Applicant's supplemental oath/declaration filed on 3/6/06 is proper and has been entered.

Claim Rejections - 35 USC § 103

The rejection of claims 1-42, 59-66, and 70-76 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,741,899 (4/21/98), hereafter referred to as Capon et al., in view of Blau et al. (1997) PNAS, Vol. 94, 3076-3081, is maintained. Applicant's amendments

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and arguments have been fully considered but have not been found persuasive in overcoming the rejection of record for reasons discussed in detail below.

The applicant argues that Capon et al. only teaches to use a saturating concentration of the inducer FKBP, a concentration shown to be ineffective in inducing dimerization of the chimeric receptors by the applicants. The applicant further argues that an artisan following the teachings of Capon when faced with a failed experiment would have had no idea why the assay failed and would have questioned the functionality of the chimeric receptors rather than the concentration of inducer used in the assay. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The rejection of record is based on the combined teachings of Capon et al. in view of Blau et al. Applicant's argument against Capon et al. is not persuasive because Blau et al. clearly teaches that in fact the chimeric receptors disclosed by Capon et al. were functional and that varying the concentration of the inducer molecule was sufficient to identify a suitable concentration of inducer to induce dimerization and signaling through the chimeric receptor in the cell line tested. Thus, the skilled artisan, familiar with Blau et al. would not question whether the chimeric receptors were functional. Instead, the skilled artisan, knowledgeable about the concentration affects of the inducer on signaling and proliferation taught in Blau et al., would simply have tested various concentrations of the inducer FKBP when practicing the methods of Capon et al.

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Therefore, since Blau et al. teaches methods to determine the optimal concentration of FK1012 to induce the dimerization of chimeric proteins comprising FKBP and EpoR in cells expressing the chimeric receptor such that the cells proliferate (Blau et al., page 3078, Figures 2 and 3), and further actually demonstrates concentrations of FK1012 effective to induce the association of the chimeric protein on cells, thereby inducing cell proliferation (Blau et al., Figures 2 and 3), Blau et al. provides sufficient motivation for testing a variety a concentrations of FK1012 to determine the optimum concentration for inducing the proliferation of cells expressing a chimeric protein comprising FKBP domains and a signaling domain according to the methods of Capon et al. The skilled artisan would further have had a reasonable expectation of success in identifying the optimum concentration of FK1012 to induce cell proliferation based on the successful demonstration in Blau et al. of the testing methods and the identification of actual concentrations of FK1012 which were effective in inducing cell proliferation in cell expressing the chimeric protein.

It is further reiterated from the previous office action that in regards to the obviousness of optimizing concentrations, the MPEP, section 2144.05 which sets forth that, “[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. ‘[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.’ *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)”. See also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of

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percentage ranges is the optimum combination of percentages."); and *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969), *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Thus, for the reasons set forth above, the rejection of record stands.

The rejection of claims 44-53, and 55-58 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,741,899 (4/21/98), hereafter referred to as Capon et al., in view of U.S. 5,994,313 (11/30/99), hereafter referred to as Crabtree et al., and Blau et al. (1997) PNAS, Vol. 94, 3076-3081, is maintained. Applicant's amendments and arguments have been fully considered but have not been found persuasive in overcoming the rejection of record for reasons discussed in detail below.

Applicant's arguments regarding the teachings of Capon et al. in view of Blau et al. have been fully addressed above and have not been found persuasive. The applicant has not presented any specific arguments regarding the teachings of Crabtree et al. Therefore, for reasons of record and in particular in view of the reasons set forth above in regards to the teachings of Capon et al. and Blau et al., the rejection of record stand.

Claim Rejections - 35 USC § 112

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The rejection of claims 12-20, and 32-40 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of applicant's amendments to the claims.

Claim Objections

The objection to Claim 57 because of informalities is withdrawn in view of applicant's amendment to claim 57.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbé', with a long horizontal flourish extending to the right.